

No clinical benefit from manual thrombus aspiration in patients with non-ST-elevation myocardial infarction

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Abstract

Introduction: There are scarce data on the usefulness of manual thrombectomy among patients with non-ST-elevation myocardial infarction (NSTEMI). Early positive reports were not supported by the clinical outcome in the recent TATORT-NSTEMI (Thrombus Aspiration in Thrombus Containing Culprit Lesions in Non-ST-Elevation Myocardial Infarction) study.

Aim: To analyze the long-term outcome of NSTEMI patients treated with manual thrombectomy during percutaneous coronary intervention (PCI) in the Polish multicenter National Registry of Drug Eluting Stents (NRDES) study.

Material and methods: There were 13 catheterization laboratories in Poland that enrolled patients in NRDES Registry in 2010–2011. Patients with a diagnosis of NSTEMI were divided into two groups: those that were treated with manual thrombectomy for their primary PCI (T) and those who were not (NT).

Results: There were 923 patients diagnosed with NSTEMI in NRDES. Aspiration thrombectomy was used in 71 (7.7%) patients and the remaining 852 (92.3%) NSTEMI cases were treated without thrombectomy during the index PCI. Thrombectomy was more often used in patients with TIMI less than 1, thrombus grades 4 and 5 and older male patients. Percutaneous coronary interventions complications such as distal embolization and slow flow were more often observed in the thrombectomy subgroup. Overall mortality at 1 year was 1.69% in the T and 5.92% in the NT group ($p = 0.24$ and $p = 0.32$ after propensity score matching adjustment with $p = 0.11$ in the multivariate logistic regression model).

Conclusions: There was no mortality benefit from thrombus aspiration in NSTEMI patients at 1-year follow-up.

Key words: myocardial infarction, registry, thrombectomy.

Introduction

It has been postulated that there are several strategies that can reduce damage to the heart muscle from ischemia-reperfusion injury [1]. Conflicting data on the effectiveness of manual thrombus aspiration in ST elevation myocardial infarction (STEMI) patients treated with primary percutaneous coronary intervention (PCI) have been recently published [2–5]. Updated myocardial revascularization guidelines from the European Society of Cardiology (ESC) advises the use of thrombectomy during primary PCI in STEMI only in selected patients, thus degrading its use to class IIb [6]. On the other hand, there are hardly any data on the usefulness of manual thrombectomy among patients with non-ST-elevation myocardial infarction (NSTEMI), with no clear guideline recommendations. Early positive reports have not been

supported by clinical outcome, e.g. in the recent TATORT-NSTEMI (Thrombus Aspiration in Thrombus Containing Culprit Lesions in Non-ST-Elevation Myocardial Infarction) study [7, 8].

Aim

Our aim was to analyze the real-life registry long-term outcome of NSTEMI patients treated with manual thrombectomy during PCI in the Polish multicenter National Registry of Drug Eluting Stents (NRDES) study. The results of this all-comers registry should provide complementary and contemporary information to the already available data.

Material and methods

The NRDES was a study based on the Polish National PCI Registry, which is a mandatory database for Polish

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catheterization laboratories since 2004 [9]. An analysis of thrombectomy value and effectiveness in STEMI patients has been previously published using the NRDES database [5, 10]. There were 13 high-volume catheterization laboratories with 24/7 PCI duty that enrolled patients in the NRDES registry in 2010–2011 (12 months of enrollment). These were the centers that agreed to fill in the extended version of the National PCI Registry called NRDES. The main aim of this analysis was to compare the outcomes of NSTEMI patients (according to the ESC definition) who were treated with manual thrombectomy (other types of thrombectomy were excluded from the analysis) for their PCI procedure (T) vs those who were not (NT). The use of thrombectomy and type of the device were left at the operators' discretion and experience in each individual case since this was a registry study with no influence on the choice of therapy. Patients who were diagnosed with NSTEMI and underwent PCI were included in the registry (there were no additional exclusion criteria). The primary end-point of this analysis was overall mortality at 12 months. Secondary clinical endpoints included: non-fatal reinfarction, definite stent thrombosis (as defined by the Academic Research Consortium – ARC) [11], urgent revascularization (PCI and/or coronary artery bypass graft (CABG)) and target vessel revascularization at 1-year follow-up. Major adverse cardiovascular events (MACE) were defined as the occurrence of death, myocardial infarction, target vessel revascularization (TVR) or urgent PCI/CABG (hierarchical). Thrombus grade category was defined according to the original paper [12]. Chronic kidney disease was defined as the presence of the disease prior to the enrollment or creatinine clearance of less than 60 ml/min/1.73 m².

The NRDES study complied with the Declaration of Helsinki and was approved by Bioethics Committee at the Jagiellonian University in Krakow, Poland (KBET/120/B/2010 at 30th September 2010).

Statistical analysis

Data were analyzed according to the established statistical standards. Categorical variables are expressed as percentages (frequency); continuous variables are expressed as mean \pm standard deviation. Normal distribution was assessed by the Shapiro-Wilk test and equality of variances using the Levene test. Between-group differences were tested by Student's or Welch's *t*-test for normally distributed or by the Mann-Whitney *U* test for non-normally distributed continuous variables. Categorical variables were compared by Pearson's χ^2 test or Fisher's exact test for 2 \times 2 tables. The risk of MACE in the 12-month follow-up was determined by univariate and multivariate logistic regression.

Due to the observational nature of the study, the statistical analysis plan included a balancing for covari-

ates step. Balancing was performed for NSTEMI subject populations with thrombectomy performed and not performed during PCI. A one-to-one matched procedure without replacement was performed. We modeled the log odds of probability of thrombectomy being performed as a function of selected confounders depending on the subpopulation. Due to the small sample size of subjects with thrombectomy performed in the NSTEMI population, nearest neighbor matching was used. This method guarantees that a match is always found for all the treated units even if the calculated propensity score values are not close. The used confounders list consisted of: access site, age, arterial hypertension, chronic kidney disease, diabetes mellitus, gender, hyperlipidemia, Killip class on admission, lower limb atherosclerosis, clopidogrel loading dose before cath lab administration, previous CABG, previous PCI, prior myocardial infarction, prior stroke, thrombus grade category, thrombolysis in myocardial infarction (TIMI) before PCI and treated vessel (Cx, Dg, IM, LAD, LMCA, Mg, RCA, SvG). Pairs obtained by propensity score matching were analyzed using paired difference tests. Continuous variables were analyzed by paired *t*-tests if the differences between pairs were normally distributed; for non-normally distributed differences the Wilcoxon signed rank test was used. Paired categorical variables were compared using the McNemar-Bowker test to assess whether differences between subjects with and without thrombectomy performed were statistically significant. Values of *p* less than 0.05 were considered statistically significant. All calculations were done with JMP, Version 9.0.0 SAS Institute Inc., Cary, NC, 1989–2007.

Power calculations were performed retrospectively. For detecting a difference in MACE rate between patients treated with manual thrombectomy and patients with no thrombectomy the sample size actually used for type I error equal to 0.05 post hoc power was 64.2%. The power would be 90% if data available for group T were twice as large assuming the same rates. It should be noted that the post-hoc power analysis has been criticized as a means of interpreting negative study results. For this reason the results of the analysis should be interpreted with caution.

Results

There were 2686 patients enrolled in the NRDES registry, of whom 923 were diagnosed with NSTEMI (34%). Aspiration thrombectomy was used in 71 (7.7%) patients and the remaining 852 (92.3%) NSTEMI patients were treated without thrombectomy during the index PCI. The thrombectomy use ranged from 2.8% to 21% in participating centers. Patient baseline demographic, angiographic, procedural and clinical characteristics in both subgroups T or NT unadjusted and adjusted are presented in Tables I and II. Thrombectomy was more often used in patients

Table I. Baseline demographics and angioplasty characteristics unadjusted

Variable	Level	NT (n = 852)	T (n = 71)	Value of p
Age [years]	–	62.8 ±11.2	66.3 ±11.7	0.01*
Gender	Male	66.2% (564)	80.3% (57)	0.02*
	Female	33.8% (288)	19.7% (14)	
Prior myocardial infarction	Yes	25.9% (221)	16.9% (12)	0.1
Arterial hypertension	Yes	82.04% (699)	77.5% (55)	0.3
Hyperlipidemia	Yes	70.5% (601)	70.4% (50)	1.0000
Diabetes mellitus	Yes	23.7% (202)	23.9% (17)	1.0000
Chronic kidney disease	Yes	6.8% (58)	1.4% (1)	0.08
Prior stroke	Yes	4.8% (41)	7.04% (5)	0.4
Previous PCI	Yes	15.9% (135)	9.9% (7)	0.2
Previous CABG	Yes	4.2% (36)	5.6% (4)	0.5
Killip class on admission	I	95.8% (816)	97.2% (69)	0.8
	II	2.5% (21)	1.4% (1)	
	III	0.8% (7)	0.0% (0)	
	IV	0.9% (8)	1.4% (1)	
Arterial access site	Femoral	85.2% (726)	81.7% (58)	0.8
	Radial	14.4% (123)	18.3% (13)	
	Brachial	0.2% (2)	0.0% (0)	
	Other	0.1% (1)	0.0% (0)	
Number of critically stenosed arteries	1-vessel disease	38.03% (324)	47.9% (34)	0.3
	2-vessel disease	39.0% (332)	39.4% (28)	
	3-vessel disease	21.5% (183)	12.7% (9)	
	LMCA and RCA disease	0.7% (6)	0.0% (0)	
	LMCA disease	0.8% (7)	0.0% (0)	
LMCA	Yes	1.3% (11)	1.4% (1)	1.0000
LAD	Yes	36.03% (307)	22.5% (16)	0.03*
Dg	Yes	8.2% (70)	8.5% (6)	0.8
IM	Yes	0.7% (6)	1.4% (1)	0.4
Cx	Yes	24.06% (205)	36.6% (26)	0.02*
Mg	Yes	14.2% (121)	8.5% (6)	0.2
RCA	Yes	29.3% (250)	35.2% (25)	0.3
SvG	Yes	1.2% (10)	4.2% (3)	0.07
Arterial graft	Yes	0.0% (0)	0.0% (0)	–
TIMI before PCI	0	18.3% (156)	73.2% (52)	< 0.0001*
	1	15.3% (130)	5.6% (4)	
	2	19.4% (165)	7.04% (5)	
	3	47.07% (401)	14.08% (10)	
GP IIb/IIIa inhibitors during PCI	Abciximab	2.2% (19)	19.7% (14)	< 0.0001*
	Eptifibatide	4.6% (39)	15.5% (11)	
	None	93.2% (794)	64.8% (46)	

Table I. Cont.

Variable	Level	NT (n = 852)	T (n = 71)	Value of p
TIMI after PCI	2 and less	1.8% (15)	2.8% (2)	0.4
	3	98.2% (837)	97.2% (69)	
Stent type	BMS	66.8% (569)	64.8% (46)	0.8
	DES	33.2% (283)	35.2% (25)	
Thrombus grade category	1	79.3% (676)	16.9% (12)	< 0.0001*
	2	11.9% (101)	21.1% (15)	
	3	3.05% (26)	12.7% (9)	
	4	2.5% (21)	15.5% (11)	
	5	3.3% (28)	33.8% (24)	
Thrombus grade category	1–3	94.3% (803)	50.7% (36)	< 0.0001*
	4–5	5.8% (49)	49.3% (35)	
PCI successful	Yes	98.9% (843)	97.2% (69)	0.2
Lesion in bifurcation	Yes	8.5% (72)	14.08% (10)	0.1
IVUS guided procedure	Yes	0.4% (3)	2.8% (2)	0.05
OCT	Yes	0.1% (1)	1.4% (1)	0.2
Side branch occlusion during PCI	Yes	0.8% (7)	0.0% (0)	1.0000
Coronary artery dissection after stent implantation	Yes	2.6% (22)	4.2% (3)	0.4
Distal embolization during PCI	Yes	0.1% (1)	2.8% (2)	0.03*
No-reflow	Yes	0.1% (1)	0.0% (0)	1.0000
Slow-flow	Yes	2.0% (17)	7.04% (5)	0.02*
Artery perforation	Yes	0.1% (1)	0.0% (0)	1.0000
Cardiac tamponade during hospitalization	Yes	0.0% (0)	0.0% (0)	–
Clopidogrel – loading dose before cath lab	300 mg	5.9% (50)	1.4% (1)	0.1
	600 mg	57.4% (489)	70.4% (50)	
	Long-term therapy	1.5% (13)	1.4% (1)	
	Without clopidogrel	35.2% (300)	26.8% (19)	
Prasugrel – loading dose before cath lab	Long-term therapy	1.4% (12)	0% (0)	0.6
	Without prasugrel	98.6% (840)	100% (71)	
Clopidogrel – loading dose in cath lab	300 mg	4.7% (40)	2.8% (2)	0.6
	600 mg	29.3% (250)	23.9% (17)	
	Long-term therapy	1.8% (15)	1.4% (1)	
	Without clopidogrel	64.2% (547)	71.8% (51)	
Prasugrel – loading dose in cath lab	60 mg	1.2% (10)	0% (0)	0.5
	Long-term therapy	0.9% (8)	0% (0)	
	Without prasugrel	97.9% (834)	100% (71)	

CABG – Coronary artery bypass graft, Cx – circumflex artery, Dg – diagonal artery, IM – intermediate artery, IVUS – intravascular ultrasound, LAD – left anterior descending artery, LMCA – left main coronary artery, Mg – marginal artery, OCT – optical coherence tomography, PCI – percutaneous coronary interventions, RCA – right coronary artery, SvG – saphenous vein graft, TIMI – Thrombolysis in Myocardial Infarction grade. Data are presented as mean ± standard deviation or number (percentage).

Table II. Baseline demographics and angioplasty characteristics adjusted

Variable	Level	NT (n = 71)	T (n = 71)	Matched pairs	Value of p
Age	–	61.9 ±11.4	62.8 ±11.2	71	0.6
Gender	Female	22.5% (16)	19.7% (14)	71	0.7
	Male	77.5% (55)	80.3% (57)		
Prior myocardial infarction	Yes	18.3% (13)	16.9% (12)	71	0.8
Arterial hypertension	Yes	81.7% (58)	77.5% (55)	71	0.6
Hyperlipidemia	Yes	70.4% (50)	70.4% (50)	71	1.0000
Diabetes mellitus	Yes	21.3% (15)	23.9% (17)	71	0.7
Chronic kidney disease	Yes	0.0% (0)	1.4% (1)	71	–
Prior stroke	Yes	4.3% (3)	7.04% (5)	71	0.5
Previous PCI	Yes	8.5% (6)	9.9% (7)	71	0.8
Previous CABG	Yes	4.2% (3)	5.6% (4)	71	0.7
Killip class on admission	I	100.0% (71)	97.2% (69)	71	–
	II	0.0% (0)	1.4% (1)		
	III	0.0% (0)	0.0% (0)		
	IV	0.0% (0)	1.4% (1)		
Access site	Femoral	81.7% (58)	81.7% (58)	71	1.0000
	Radial	18.3% (13)	18.3% (13)		
Number of critically stenosed arteries	1-vessel disease	36.6% (26)	47.9% (34)	71	0.6
	2-vessel disease	40.85% (29)	39.44% (28)		
	3-vessel disease	19.72% (14)	12.68% (9)		
	LMCA and RCA disease	2.82% (2)	0.00% (0)		
LMCA	Yes	0.0% (0)	1.4% (1)	71	–
LAD	Yes	29.6% (21)	22.5% (16)	71	0.4
Dg	Yes	9.9% (7)	8.5% (6)	71	0.8
IM	Yes	1.4% (1)	1.4% (1)	71	1.0000
Cx	Yes	29.6% (21)	36.6% (26)	71	0.4
Mg	Yes	4.2% (3)	8.5% (6)	71	0.3
RCA	Yes	35.2% (25)	35.2% (25)	71	1.0000
SvG	Yes	2.8% (2)	4.2% (3)	71	0.7
Arterial graft	Yes	0.0% (0)	0.0% (0)	71	–
TIMI before PCI	0	64.8% (46)	73.2% (52)	71	0.6
	1	5.6% (4)	5.6% (4)		
	2	9.9% (7)	7.04% (5)		
	3	19.7% (14)	14.08% (10)		
GP IIb/IIIa inhibitors during PCI	Abciximab	4.2% (3)	19.7% (14)	71	0.03*
	Eptifibatide	11.3% (8)	15.5% (11)		
	None	84.5% (60)	64.8% (46)		
TIMI after PCI	2 and less	4.2% (3)	2.8% (2)	71	0.7
	3	95.8% (68)	97.2% (69)		

Table II. Cont.

Variable	Level	NT (n = 71)	T (n = 71)	Matched pairs	Value of p
Stent type	BMS	63.4% (45)	64.8% (46)	71	0.9
	DES	36.6% (26)	35.2% (25)		
Thrombus grade category	1	21.1% (15)	16.9% (12)	71	1.0
	2	21.1% (15)	21.1% (15)		
	3	15.5% (11)	12.7% (9)		
	4	14.08% (10)	15.5% (11)		
	5	28.2% (20)	33.8% (24)		
Thrombus grade category	1–3	42.3% (30)	49.3% (35)	71	0.3
	4–5	57.8% (41)	50.7% (36)		
Clopidogrel – loading dose before cath lab	300 mg	1.4% (1)	1.4% (1)	71	0.8
	600 mg	67.6% (48)	70.4% (50)		
	Long-term therapy	0.0% (0)	1.4% (1)		
	Without clopidogrel	31.0% (22)	26.8% (19)		
Prasugrel – loading dose before cath lab	Long-term therapy	2.8% (2)	0.0% (0)	71	–
	Without prasugrel	97.2% (69)	100.0% (71)		
Clopidogrel – loading dose in cath lab	300 mg	5.6% (4)	2.8% (2)	71	0.9
	600 mg	16.9% (12)	23.9% (17)		
	Long-term therapy	1.4% (1)	1.4% (1)		
	Without clopidogrel	76.06% (54)	71.8% (51)		
Prasugrel – loading dose in cath lab	60 mg	5.63% (4)	0.0% (0)	71	–
	Long-term therapy	1.4% (1)	0.0% (0)		
	Without prasugrel	93.0% (66)	100.0% (71)		

CABG – Coronary artery bypass graft, Cx – circumflex artery, Dg – diagonal artery, IM – intermediate artery, LAD – left anterior descending artery, LMCA – left main coronary artery, Mg – marginal artery, PCI – percutaneous coronary interventions, RCA – right coronary artery, SvG – saphenous vein graft, TIMI – Thrombolysis in Myocardial Infarction grade. Data are presented as mean ± standard deviation or number (percentage).

with TIMI less than 1, thrombus grade 4 and 5, as well as older male patients. The PCI complications such as distal embolization and slow flow were more often observed in the thrombectomy subgroup. Primary and secondary endpoints of the analysis unadjusted and with adjustment by propensity score matching are depicted in Tables III and IV. Overall mortality at 1 year was 1.7% in group T and 5.9% in group NT ($p = 0.2$ and $p = 0.3$ after propensity score matching adjustment). There was an overall trend of more frequent MACE occurrence in the NT group, but it was non-significant. Unadjusted Kaplan-Meier survival curves and MACE curves for both groups are shown in Figures 1 and 2. Subgroup analyses showed no significant benefit from thrombus aspiration in selected subsets of patients (thrombus grade category, age, diabetes, target artery). Results from the multivariate logistic regression model revealed that thrombectomy use during PCI for NSTEMI was not an independent predictor of MACE at 12 months – Table V.

Discussion

Whereas there are multiple trials and registries addressing the issue of thrombectomy use in the STEMI setting [3–5, 13, 14], the NRDES study is one of only a few existing in the PubMed database that discuss the use of manual aspiration thrombectomy in the NSTEMI subgroup of patients [15]. The data are complementary to those of other trials, since they represent real-life all-comers registry data from multiple centers in Poland. Previous studies have discarded its use and have proven no benefit for surrogate endpoints such as microvascular obstruction and infarct size [8]. Moreover, even though thrombus burden is present in visual assessment in up to 70% of NSTEMI cases and the notion of mechanical removal of thrombus seems plausible, the results of a randomized trial and in a real life population of the NRDES registry have not shown its beneficial effect [7, 16]. Current ESC guidelines give no specific recommendation on the use of thrombectomy in NSTEMI and have downgraded its use in the

Table III. Unadjusted primary and secondary outcomes at 1 year

1-year outcome	NT (n = 852) (%)	T (n = 71) (%)	Value of p
Death	5.9	1.7	0.2
Stent thrombosis	0.4	0.0	1.0000
TVR	2.2	0.0	0.6
reMI	4.7	0.0	0.2
Urgent PCI	8.2	3.7	0.4
Urgent CABG	0.4	3.7	0.049*
Urgent PCI or urgent CABG	8.6	5.6	0.6
MACE	16.8	7.3	0.08

CABG – Coronary artery bypass graft, MACE – major adverse cardiovascular event, PCI – percutaneous coronary intervention, reMI – recurrent myocardial infarction, TVR – target vessel revascularization. Data are presented as number (percentage).

Table IV. Adjusted primary and secondary outcomes at 1 year

1-year outcome	NT (n = 71) (%)	T (n = 71) (%)	Matched pairs	Value of p
Death	5.8	1.9	52	0.3
Stent thrombosis	0.0	0.0	36	–
TVR	5.6	0.0	36	–
reMI	2.8	0.0	36	–
Urgent PCI	11.1	5.6	36	0.4
Urgent CABG	0.0	5.6	36	–
Urgent PCI or CABG	11.1	8.3	36	0.7
MACE	17.5	10.0	40	0.4

CABG – Coronary artery bypass graft, MACE – major adverse cardiovascular event, PCI – percutaneous coronary intervention, reMI – recurrent myocardial infarction, TVR – target vessel revascularization. Data are presented as number (percentage).

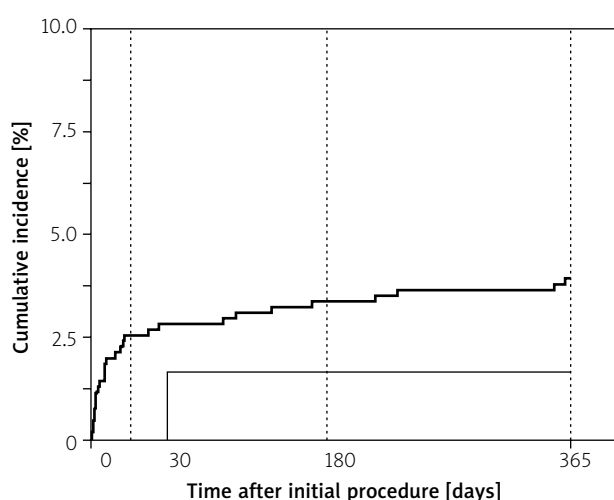
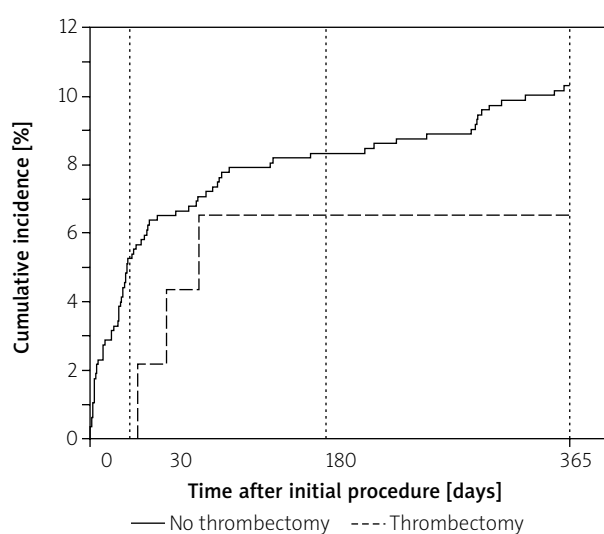
**Figure 1.** Kaplan-Meier survival curves for 1 year observation in T (thin line) vs. NT (thick line) groups respectively (log-rank test; adjusted results; $p = 0.3$)**Figure 2.** Kaplan-Meier major adverse cardiovascular event curves for 1 year observation in T (dotted line) vs. NT (fine line) groups respectively (log-rank test; adjusted results; $p = 0.2$)

Table V. Logistic regression models for 12-month major adverse cardiovascular event occurrence

Variable	OR	Univariate		Multivariate ^a		Multivariate ^b	
		OR (95% CI)	Value of <i>p</i>	OR (95% CI)	Value of <i>p</i>	OR (95% CI)	Value of <i>p</i>
Age	10 years	1.3 (1.07–1.6)	0.009*	1.2 (1.02–1.5)	0.03*	1.3 (1.03–1.5)	0.02*
Gender	Male/female	0.8 (0.5–1.3)	0.4				
Prior myocardial infarction	Yes/no	1.8 (1.08–2.8)	0.02*	1.6 (1.0–2.6)	0.05	1.8 (1.1–3.02)	0.02*
Prior stroke	Yes/no	1.4 (0.5–3.3)	0.5				
Previous PCI	Yes/no	1.3 (0.7–2.4)	0.3				
Previous CABG	Yes/no	0.4 (0.07–1.5)	0.2			0.3 (0.05–1.2)	0.09
Arterial hypertension	Yes/no	0.8 (0.5–1.3)	0.3			0.6 (0.4–1.1)	0.1
Hyperlipidemia	Yes/no	1.0 (0.6–1.6)	0.9				
Diabetes mellitus	Yes/no	1.3 (0.8–2.1)	0.3				
Chronic kidney disease	Yes/no	1.8 (0.8–3.8)	0.2				
TIMI 3 before PCI	Yes/no	0.8 (0.5–1.3)	0.4				
TIMI 3 after PCI	Yes/no	0.6 (0.2–2.6)	0.4				
LMCA	Yes/no	2.7 (0.6–10.2)	0.2				
LAD	Yes/no	0.9 (0.6–1.4)	0.6				
Access site	Femoral/radial	1.2 (0.7–2.2)	0.8				
Stent type	BMS/DES	1.1 (0.7–1.8)	0.6				
Thrombectomy	Yes/no	0.4 (0.1–1.0)	0.04*	0.5 (0.1–1.2)	0.1	0.5 (0.1–1.2)	0.1

^aModel fitted using backward stepwise regression (all listed variables initially included) with the Wald χ^2 $p < 0.05$ threshold stopping rule with the locked thrombectomy (the Wald χ^2 computed as $(\text{Estimate}/\text{Std Error})^2$ for the hypothesis that the parameter is zero shows the prior myocardial infarction parameter to be statistically significant with $p = 0.0499$; at the same time the likelihood-ratio χ^2 test calculated as twice the difference of the log-likelihoods between the full model and the model constrained by the hypothesis to be tested shows the parameter to be not statistically significant with $p = 0.0539$). ^bModel fitted using backward stepwise regression (all listed variables initially included) with the minimum corrected Akaike information criterion stopping rule with the locked thrombectomy. CABG – Coronary artery bypass graft, CI – confidence interval, LAD – left anterior descending, LMCA – left main coronary artery, OR – odds ratio, PCI – percutaneous coronary intervention, TIMI – thrombolysis in myocardial infarction grade. Data are presented as odds ratio with 95% confidence interval and number (percentage).

STEMI population [6], largely due to the negative results of recent large trials and a meta-analysis [2–4]. Moreover, a recent survey revealed that aspiration thrombectomy is used routinely by 36% of physicians during PCI for STEMI and selectively in 60% of cases [17]. There is also reported a strong belief (89%) among interventional cardiologists that a confirmatory thrombectomy trial is needed. That is why we believe it is important to show our data as another layer of evidence in the poorly investigated issue of thrombectomy use in NSTEMI patients in contrast to the STEMI subgroup, which even in the presence of multiple data is still burdened with uncertainty as to the procedure. In the NRDES registry, the use of thrombectomy in NSTEMI patients was fairly rare (in up to 8% of patients) in comparison to STEMI [5], which suggests that it may have only been used in cases that seemed the most suitable ones for thrombus aspiration. Even though a bias to use thrombus aspiration in the case of a large thrombus burden, in older male patients and in the circumflex artery has been noted, still it was less pronounced than in the same population for the STEMI subgroup [5]. Half of the patients in our study where thrombectomy was used had a thrombus grade category 4–5, whereas in the no

thrombectomy group it was only 5.8%. This means that if thrombus was visible, aspiration was considered by the attending PCI operator. This was in fact the greatest bias that needed to be addressed by the statistical methodology to account for obvious baseline differences. The numerical difference between the thrombectomy and no thrombectomy group with regard to 1-year mortality both unadjusted and adjusted by propensity score matching is substantial but not statistically significant. Even though the T group was considered higher risk by demographics and angiography, it revealed lower mortality in long-term observation. Nevertheless, it should be noted here that the difference was not significant when either adjusted or unadjusted data were compared and may simply be a matter of chance, not reflecting a real difference. The observed mortality rates are also lower than in the previously published Polish data [18], which may reflect changing trends in treatment of acute MI in Poland over the years [19]. All the above might be the trigger to initiate a large trial focused on clinical endpoints in a selected cohort of NSTEMI patients with a visible thrombus burden. The NSTEMI patients are a heterogeneous group of patients often with a more aggravating past medical

history and outcome even in comparison to STEMI [20, 21] and certainly require scrutinized research on a specific subgroup of patients.

There was no angiographic source data verification by an independent PCI operator or corelab. No standardized procedure description was available and thrombectomy was performed according to local standards. Finally, the subgroup of NSTEMI patients with thrombectomy was too small (smaller than in e.g. the TATORT trial) to draw any definite conclusions.

Conclusions

Use of aspiration thrombectomy in NSTEMI is rare in real life populations. There exists a selection bias for performing thrombectomy, especially in patients with a large thrombus burden. There was no mortality benefit after statistical adjustments from thrombus aspiration in NSTEMI patients at 1-year follow-up in this real-life all-comers multicenter registry. The rate of MACE was also similar.

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Conflict of interest

The authors declare no conflict of interest.

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